

PTO/SB/08A (08-03)

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet 1 of 13**Complete if Known**

Application Number	09/468,496
Filing Date	December 21, 1999
First Named Inventor	Ron Waksman et al.
Art Unit	3763
Examiner Name	M. Desanto
Attorney Docket Number	WELD 111 DIV IV

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
AFD		US- 1,406,509	02-14-1922	Viol	
		US- 1,753,287	04-08-1930	Failla	
		US- 1,786,373	12-23-1930	Walker	
		US- 2,830,190	04-08-1958	Karp	
		US- 3,145,181	08-18-1964	Courtois, et al.	
		US- 3,154,501	10-27-1964	Hertz	
		US- 3,168,092	02-02-1965	Silverman	
		US- 3,324,847	06-13-1967	Zoumboulis	
		US- 3,351,049	11-07-1967	Lawrence	
		US- 3,532,888	10-06-1970	Masefield, et al.	
		US- 3,589,356	06-29-1971	Silverman	
		US- 3,600,568	08-17-1971	Weyrauch	
		US- 3,632,520	01-04-1972	Garber	
		US- 3,659,107	04-25-1972	Selle, et al.	
		US- 3,669,093	06-13-1972	Sauerwein, et al.	
		US- 3,674,006	07-04-1972	Holmer	
		US- 3,811,426	05-21-1974	Culver, et al.	
		US- 3,872,856	03-25-1975	Clayton	
		US- 3,927,325	12-16-1975	Hungate, et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁴
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
AFD		CA 1197631	12-03-1985	Leung, et al.		
		DE 1 065 989	09-24-1959	Rusch K. G.		
		DE 1 466 774	06-04-1969	Buchler & Co.		
		DE 3620123	12-17-1987	Vasold, et al.		
		DE 3 643 893 A1	06-30-1988	Buchler GmbH		
		DE 3739749A1	06-08-1989	Schreier		

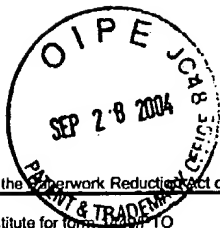
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Sheet 2 of 13**Complete if Known**

Application Number	09/468,496
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Examiner Name	M. Desanto
Attorney Docket Number	WELD 111 DIV IV

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		Number-Kind Code ² (if known)			
APD		US- 4,096,862	06-27-1978	DeLuca	
		US- 4,202,323	05-13-1980	Zweig, et al.	
		US- 4,233,517	11-11-1980	van't Hooft	
		US- 4,250,887	02-17-1981	Dardik, et al.	
		US- 4,292,960	10-06-1981	Paglione	
		US- 4,323,055	04-06-1982	Kubiatowicz	
		US- 4,385,635	05-31-1983	Ruiz	
		US- 4,434,788	03-06-1984	Nakatsugawa	
		US- 4,562,001	12-31-1985	Vietzke, et al.	
		US- 4,578,061	03-25-1986	Lemelson	
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		US- 4,601,699	07-22-1986	Crain	
		US- 4,654,171	03-31-1987	Boneoeur, et al.	
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		US- 4,676,258	06-30-1987	Inokuchi, et al.	
		US- 4,697,575	10-06-1987	Horowitz	
		US- 4,702,228	10-27-1987	Russell, Jr., et al.	

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		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
MPA		DE 91 02 312.2 U1	08-06-1992	Weigl, et al.		
		EP 0 152 124	08-21-1985	van't Hooft		
		EP 0 433 011 A1	06-19-1991	Fischell et al.		
		EP 0 433 011 B1	06-19-1991	Fischell et al.		
		EP 0 448 004 A2	08-25-1991	Weigl, et al.		
		EP 0 448 004 A3	08-25-1991	Weigl, et al.		

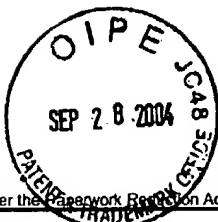
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 3 of 13

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Application Number	09/468,496
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First Named Inventor	Ron Waksman et al.
Art Unit	3763
Examiner Name	M. Desanto
Attorney Docket Number	WELD 111 DIV IV

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Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
MJD		US- 4,706,652	11-17-1987	Horowitz	
		US- 4,726,916	02-23-1988	Aubert, et al.	
		US- 4,733,665	03-29-1988	Palmaz	
		US- 4,762,129	08-09-1988	Bonzel	
		US- 4,763,642	08-16-1988	Horowitz	
		US- 4,763,671	08-16-1988	Goffinet	
		US- 4,768,507	09-06-1988	Fischell, et al.	
		US- 4,770,653	09-13-1988	Shturman	
		US- 4,784,116	11-15-1988	Russell, Jr., et al.	
		US- 4,815,449	03-28-1989	Horowitz	
		US- 4,819,618	04-11-1989	Liprie	
		US- 4,842,590	06-27-1989	Tanabe, et al.	
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		US- 4,861,520	08-29-1989	van't Hooft, et al.	
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		US- 4,891,165	01-02-1990	Suthanthiran	
		US- 4,897,076	01-30-1990	Puthawala, et al.	
		US- 4,946,435	08-07-1990	Suthanthiran, et al.	

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		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
MJD		EP 0 447 745 A2	09-25-1991	Fritz		
/		EP 0 497 495 A2	08-05-1992	Roubin, et al.		
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		EP 0 688 580 A1	12-27-1995	Verin, et al.		
		EP 0 829 271 A2	03-18-1998	Liprie		

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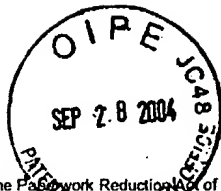
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Sheet 4 of 13

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Application Number	09/468,496
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Art Unit	3763
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Attorney Docket Number	WELD 111 DIV IV

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MRD		US- 4,994,013	02-19-1991	Suthanthiran, et al.	
		US- 5,019,075	05-28-1991	Spears, et al.	
		US- 5,030,194	07-09-1991	van't Hooft	
		US- 5,040,548	08-20-1991	Yock	
		US- 5,053,033	10-01-1991	Clarke	
		US- 5,059,166	10-22-1991	Fischell, et al.	
		US- 5,084,002	01-28-1992	Liprie	
		US- 5,103,395	04-07-1992	Spako, et al.	
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		US- 5,199,939	04-16-1993	Dake, et al.	
		US- 5,209,730	05-11-1993	Sullivan	
		US- 5,213,561	05-25-1993	Weinstein, et al.	
		US- 5,224,933	07-06-1993	Bromander	
		US- 5,267,960	12-07-1993	Hayman, et al.	

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		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
MRD		GB 793,158	04-09-1958	Rummert		
		GB 1 219 604 A	01-20-1971	Nuclesa-Nuclear		
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		GB 1 558 127 A	12-19-1979	van't Hooft		
		JP 58-78654	03-09-1982	Oximetrix		
		WO 90/03827	04-19-1990	Hayman, et al.		

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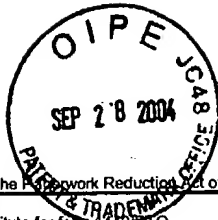
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MPN		US- 5,282,781	02-01-1994	Liprie	
		US- 5,302,168	04-12-1994	Hess	
		US- 5,304,228	04-19-1994	Prince	
		US- 5,306,244	04-26-1994	Shiber	
		US- 5,322,499	06-21-1994	Liprie	
		US- 5,327,885	07-12-1994	Griffith	
		US- 5,342,283	08-30-1994	Good	
		US- 5,354,257	10-11-1994	Roubin, et al.	
		US- 5,354,774	10-11-1994	Deckelbaum, et al.	
		US- 5,395,300	03-07-1995	Liprie	
		US- 5,405,309	04-11-1995	Carden, Jr.	
		US- 5,411,466	05-02-1995	Hess	
		US- 5,417,653	05-23-1995	Sahota, et al.	
		US- 5,460,592	10-24-1995	Langton, et al.	
		US- 5,474,531	12-12-1995	Carter	
		US- 5,476,472	12-19-1995	Dormandy, Jr., et al	
		US- 5,484,384	01-16-1996	Fearnot	
		US- 5,498,227	03-12-1996	Mawad	
		US- 5,503,613	04-02-1996	Weinberger	

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MPN		WO 93/04735	03-18-1993	Shefer, et al.		
MPN		WO 96/11303 A	05-09-1996	Novoste Corp.		

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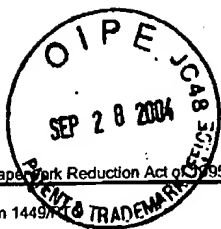
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NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
MFD	1	NISAR SYED A.M., FEDER B., "Technique of After-Loading Interstitial Implants", Syed/Feder, Radiologia Clinica 46:458-476 (1977).	
	2	NISAR SYED et al., "Combination of External and Interstitial Irradiation in the Primary Management of Breast Carcinoma", CANCER vol. 46, No. 6, pp. 1360-1365 (1980).	
	3	PUTHAWALA et al., "Temporary Iridium 192 Implant in the Management of Carcinoma of the Prostate", ENDOCURIETHERAPY/HYPERTHERMIA ONCOLOGY 1:25-34 (1985).	
	4	NISAR SYED et al., "Transperineal Interstitial-Intracavitary "Syed-Neblett" Applicator in the Treatment of Carcinoma of the Uterine Cervix", ENDOCURIETHERAPY/HYPERTHERMIA ONCOLOGY 2:1-13 (1985).	
	5	NISAR SYED A.M. et al., "Intraluminal Irradiation in the Treatment of Esophageal Cancer", ENDOCURIETHERAPY/HYPERTHERMIA ONCOLOGY 3:105-113 (1987).	
	6	FAXON et al., "Mechanism of Angioplasty and Its Relation to Restenosis", AMERICAN JOURNAL OF CARDIOLOGY 15:5B-9B (1987).	
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	9	MCCORMICK et al., "Breast Cancer", Chpt. 25 of INTERSTITIAL BRACHYTHERAPY 221-226 (1990).	

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Date

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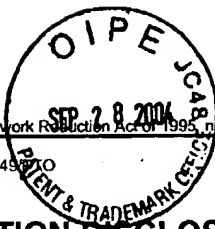
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Complete if Known

Application Number	09/468,496
Filing Date	December 21, 1999
First Named Inventor	Ron Waksman et al.
Art Unit	3763
Examiner Name	M. Desanto
Attorney Docket Number	WELD 111 DIV IV

Sheet 8 of 13

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
MFD	10	DAWSON, "Theoretic Considerations Regarding Low-Dose Radiation Therapy for Prevention of Restenosis after Angioplasty", THE READING HOSPITAL & MEDICAL CENTER 18(1) 4-7 (1991).	
	11	Skin, p. 261 of the American Medical Association Family Medical Guide, Editor Kunz.	
	12	Endovascular Low-Dose Irradiation Inhibits Neointima Formation after Coronary Artery Balloon Injury in Swine - A Possible Role for Radiation Therapy in Restenosis Prevention,	
		by Ron WAKSMAN, MD; Keith A. ROBINSON, PhD; Ian R. CROCKER, MD; Michael B. GRAVANIS, MD; Gustavo D. CIPOLLA, DVM; Spencer B. KING III, MD, CIRCULATION vol. 91, No. 5, pp. 1533	
		-1539 (Mar. 1, 1995). Submitted for publication Oct. 3, 1994.	
	13	Endovascular Low-Dose Irradiation Inhibits Neointima Formation after Coronary Artery Balloon Injury in Swine - A Possible Role for Radiation Therapy in Restenosis Prevention,	
		by Ron WAKSMAN, MD; Keith A. ROBINSON, PhD; Ian R. CROCKER, MD; Gustavo D. CIPOLLA, DVM; Spencer B. KING III, MD. Submitted for publication Mar. 25, 1994.	
	14	SCHWARTZ et al., "Effect of External Beam Irradiation on Neointimal Hyperplasia after Experimental Coronary Artery Injury", American College of Cardiology, JACC vol. 19,	
		No. 5, (Apr. 1992), pp. 1106-1113.	
	15	STEIDLE, B., "Preventative Percutaneous Radiation Therapy to Avoid Hyperplasia of the Intima after Angioplasty Combined with Stent Implantation", STRAHLENTHER ONKOL, (1994),	

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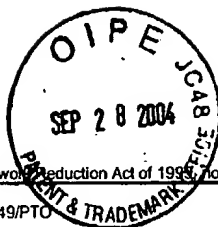
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MFD		170:151-154.	
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	17	ABBAS et al., "External Beam Irradiation Inhibits Neointimal Hyperplasia Following Balloon Angioplasty", INTERNATIONAL JOURNAL OF CARDIOLOGY, 44 (1994), 191-202.	
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Sheet	10	of	13
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AFD		Circulation, vol. 90, No. 6, (Dec. 1994), pp. 2956-2963.	
	22	FRIEDMAN, "Pathogenesis of the Spontaneous Atherosclerotic Plaque", ARCHIVES OF PATHOLOGY, vol. 76, (Sept. 1963), 94-105.	
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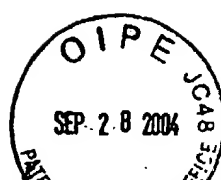
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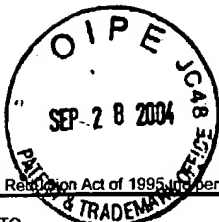
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Complete if Known	
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Sheet 11 of 13	Attorney Docket Number	WELD 111 DIV IV	

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MFD		MEDICINE, p. 496 (Aug. 25, 1994).	
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	35	GLAGOV, S., "Intimal Hyperplasia, Vascular Modeling, and the Restenosis Problem", CIRCULATION, vol. 89, No. 6, pp. 2888-2891 (Jun. 1994).	
	36	BOTTCHER et al., "Endovascular Irradiation - A New Method to Avoid Recurrent Stenosis after Stent Implantation in Peripheral Arteries: Technique and Preliminary Results", I.J.	
✓		RADIATION ONCOLOGY, BIOLOGY, PHYSICS, vol. 29, (Nov. 1994), 183-186.	

Examiner Signature	<i>M. Desanto</i>	Date Considered	12/12/04
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MED	37	LIERMANN et al. "Prophylactic Endovascular Radiotherapy to Prevent Intimal Hyperplasia after Stent Implantation in Femoropopliteal Arteries", CARDIOVASCULAR AND INTERVENTIONAL RADIOLOGY, (1994), 17:12-16.	
	38	Supplementary European Search Report - EP 97 92 2288.	
	39	Annex to the European Search Report on European Patent Application No. EP 97 92 2288.	
	40	HERRMAN, J., et al., "Pharmacological Approaches to the Prevention of Restenosis Following Angioplasty", DRUGS, 46(1): pp. 18-52 (1993).	
	41	LANGE, R., et al., "Southwestern Internal Medicine Conference: Restenosis: The Achilles Heel of Coronary Angioplasty", AMER. J. OF THE MEDICAL SCIENCES, vol. 306, pp. 265-273 (Oct. 1993)	
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✓	43	WEIDERMANN, J., et al., Abstract: "Intracoronary Irradiation Markedly Reduces Restenosis after Balloon Angioplasty in a Porcine Model", Supplement of CIRCULATION, vol. 88,	

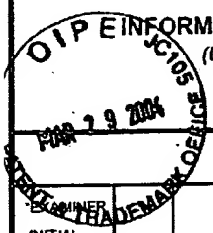
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9279.79

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10/757,744

Michael James Pratt et al.

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January 15, 2004

GROUP
Unknown

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
med	1	6,478,151	11/12/02	Schmidt et al.	206	315.5	09/07/01
	2	6,357,586	03/19/02	Pratt et al.	206	315.9	05/23/00
	3	6,131,733	10/17/00	Ergle et al.	206	315.1	03/29/99
	4	5,988,379	11/23/99	Yearous	206	315.3	08/18/98
	5	5,899,371	05/04/99	Weliver	224	245	02/26/98
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	7	5,560,749	10/01/96	Madison et al.	8	111	06/06/95
	8	5,425,452	06/20/95	Shanks et al.	206	315.7	06/20/94
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FOREIGN PATENT DOCUMENTS

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							YES	NO
		None						

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

		None

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MPS	12	5,269,410	12/14/93	Abregano	206	315.5	09/28/92
	13	5,222,588	06/29/93	Yamazoe.	206	315.5	12/11/90
	14	5,176,253	01/05/93	Perrin et al.	206	315.5	01/03/92
	15	4,869,365	09/26/89	Perdue t al.	206	315.5	07/11/88

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Sheet	1	of	2
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U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (Patent no.)	Publication Date M-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
PMJ	1	US- 5,618,266	04-08-1997	Liprie	
	2	US- 5,683,345	11-04-1997	Waksman et al.	
	3	US- 4,471,765	09-18-1984	Strauss et al.	
	4	US- 5,472,403	12-05-1995	Cornacchia et al.	
	5	US- 6,071,227	06-06-2000	Popowski et al.	
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		Country Code ² Number ⁴ Kind Code ³ (if known)	MM-DD-YYYY			
PS	6	SU 279,814	09-1975	Rimman et al.		

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